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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/832,355	04/10/2001	Imre Kovesdi	205654	9085

23460 7590 10/23/2002

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EXAMINER
SPECTOR, LORRAINE

ART UNIT	PAPER NUMBER
1647	

DATE MAILED: 10/23/2002

13

Please find below and/or attached an Office communication concerning this application or proceeding.

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APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO.

EXAMINER	

ART UNIT	PAPER NUMBER
	13

DATE MAILED: 10-23-02

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

☒ Responsive to communication(s) filed on 7/16/02

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-46 is/are pending in the application.
Of the above, claim(s) 8, 15, 20-27 is/are withdrawn from consideration.
☐ Claim(s) _____ is/are allowed.
☒ Claim(s) 1-7, 9-12, 14-19, 28-46 is/are rejected.
☐ Claim(s) _____ is/are objected to.
☒ Claim(s) 1-46 are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
☐ The specification is objected to by the Examiner.
☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.
☐ received in Application No. (Series Code/Serial Number) _____.
☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of Reference Cited, PTO-892 ✓
☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 6-9, 12 ✓ has filed w/ application
☐ Interview Summary, PTO-413
☐ Notice of Draftperson's Patent Drawing Review, PTO-948
☐ Notice of Informal Patent Application, PTO-152

--SEE OFFICE ACTION ON THE FOLLOWING PAGES--

★ U.S. GPO: 1998-421-632/40206

Part III: Detailed Office Action

Species Election Requirement:

Applicant's election with traverse of the species HBNF in Paper No. 11, filed 7/23/02 is acknowledged. The traversal is on the ground(s) that the examination of the entire application would not constitute a burden to search. This is not found persuasive because a search is directed to references which would render the invention obvious, as well as references directed to anticipation of the invention, and therefore requires a search of relevant literature in many different areas of subject matter. As the genus is anticipated by the prior art (see below), unity of invention is lacking, and each recited species requires a separate search and consideration of the prior art both for determination of obviousness under 35 U.S.C. § 103(a), and for enablement.

The requirement is still deemed proper and is therefore made FINAL.

Claims 8, 13, and 20-27, identified by applicants as not corresponding to the elected species, are ~~under~~ withdrawn from consideration.

Formal Matters:

Claim 30 is objected to: the third line of the claim should read 'or *a* combination thereof'. Correction is required.

Double Patenting Rejections:

Objections and Rejections under 35 U.S.C. §112:

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2-7, 9-12, 17, and 31 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is noted that there are several known VEGF receptors:

Flt-1 is human VEGF receptor-1 (VEGFR-1)

KDR is human VEGF receptor-2 (VEGFR-2)

Flk-1 is murine VEGFR-2

There are also "flt/flk receptors", such as Flk-2, that *do not bind VEGF*. Therefore, it is not clear what the limitation that "the first peptide portion comprises a VEGF peptide portion which exhibits a higher affinity for KDR receptors than the flt/flk receptors" imparts to claim 2, as it is not clear to which "flk/flt" receptors are referred (i.e. any in particular? all?). It is further noted that since KDR/Flk-1 are the 'high affinity' VEGF receptors, and that human VEGF would be expected to have the same or higher affinity for KDR than for Flk-1 (the murine counterpart), that in applying the art below, the Examiner finds that *if* the claim language were intended to mean *any* flk/flt receptor, that human VEGF would inherently meet that limitation.

Claim 5 is indefinite because $VEGF_{121}$ cannot have a lower affinity for neurophilin-1 or -2 than itself.

Claim 6 is indefinite because it is not clear whether "or both" means a protein consisting essentially of both proteins, in which case the claim is non-functional, or alternatively that the fusion protein has a half-life at least twice that of each of the individual proteins that it comprises, or alternatively that the fusion protein has half-life at least twice the combined half-lives of its component parts. Claim 9 is similarly indefinite; it cannot be determined if "or both" means that the protein is more angiogenic than either of its components, or than both of the components together.

It is not clear what parameters are intended by "greater maturity" as recited in claim 11 are. Without a clear indication of such, the metes and bounds of the claim cannot be determined.

Claim 17 is indefinite because it is not clear what "dilatation" is with respect to blood vessel walls.

Claim 31 is indefinite because of the repeated use of the open term "comprises"; it cannot be determined whether or not the claim is limited in scope to species less than or equal to 60% of the length of WT HBNF or MK, as the term "comprises" would allow the inclusion of additional sequence. For the purpose of compact prosecution, the claim is being interpreted as reading on the

full-length proteins.

The remaining claims are rejected for depending from an indefinite claim.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

10/21/02

Claims 1-7, 9-12, 14-19, 28-46 ~~8, 13, and 20-27~~ are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, and as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention in a manner commensurate in scope with the claims.

Now VEGF-A 0% to 80% Vegf

The claims in this application are extremely broad, encompassing a fusion of any possible VEGF protein that does not bind heparin, to any other cytokine with any angiogenic or bone growth activity. Overall, the specification does not teach how to make and use the invention in a manner commensurate in scope with the claims, and does not provide an adequate written description to support the claimed scope. There are many individual issues that lead to this conclusion:

1) The specification does not provide adequate written description or enablement of the scope of claimed "VEGF" molecules, including lack of written description or enablement of VEGF with less affinity for neurophilin-1 or -2 than $VEGF_{121}$.

The specification provides a very broad and sweeping definition of VEGF at pages 2-8, including, for example, "a peptide exhibiting high levels of hydrophobicity/hydrophilicity conservation to a naturally occurring" VEGF. Hence, read in light of the specification, the term "VEGF" reads on all possible functional equivalents. The specification provides neither an adequate written description of such equivalents, nor does it enable the scope of such.

With respect to written description, *Vas-Cath Inc. v. Mahurkar*, 19USPQ2d 1111, clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention.* The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See *Vas-Cath* at page 1116).

With the exception of the known forms of VEGF, in particular $VEGF_{121}$, $VEGF_{165}$, and $VEGF_{110}$ and art recognized derivatives thereof, the skilled artisan cannot envision the detailed chemical structure of the encompassed VEGF proteins, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.

One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481 at 1483. In *Fiddes*, claims directed to mammalian FGF's were found to be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence.

Therefore, only known VEGF proteins, but not the full breadth of the claims, which encompass all possible functional equivalents, meet the written description provision of 35 U.S.C. §112, first paragraph. Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision (see page 1115).

With respect to enablement, the factors considered when determining if the disclosure satisfies the enablement requirement and whether any necessary experimentation is "undue" include, but are not limited to:

1) nature of the invention, 2) state of the prior art, 3) relative skill of those in the art, 4) level of predictability in the art, 5) existence of working examples, 6) breadth of claims, 7) amount of direction or guidance by the inventor, and 8) quantity of experimentation needed to make or use the invention. *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

The nature of the invention is fusion proteins combining the activities of two proteins with angiogenic or bone growth promoting activity. The state of the prior art is that such proteins are known (see art rejections below), but that such are known with well defined cytokines. The relative skill in the art is high, but predictability is low. The art of protein engineering is an unpredictable one, and it is not recognized as routine to make functionally equivalent proteins. There are no working examples of derivatives of VEGF or functional equivalents thereof, and the laundry list of possible changes or properties that could be investigated is merely an invitation to experiment and develop such molecules, as opposed to being constructive guidance. Accordingly, given that one would have to 'make and test' all possible species, taken with the lack of guidance and working examples and the unpredictability of the art, it would require undue experimentation to practice the invention in a manner commensurate in scope with the claims. It was found in *Ex parte Maizel* (27 USPQ2d 1662 at 1665) that:

> Appellants have not chosen to claim the DNA by what it is but, rather, by what it does, i.e., encoding either a protein exhibiting certain characteristics, *or* a biologically functional equivalent thereof. Appellants' claims might be analogized to a single means claim of the type disparaged by the Court of Customs and Patent Appeals in *In re Hyatt,* 708F.2d 712, 218 USPQ 195 (Fed. Cir. 1983). The problem with the phrase "biologically functional equivalent thereof" is that it covers any conceivable means, i.e., cell or DNA, which achieves the stated biological result while the specification discloses, at most, only a specific DNA segment known to the inventor. Clearly the disclosure is not commensurate in scope with the claims."

As was the case in *Maizel*, applicants are claiming a protein (and DNA encoding such) by particular characteristics, without regard to structure, in a manner approaching a single means claim, which is not enabled by the specification as originally filed.

Further, claim 1 recites that the VEGF portion may have bone growth promoting activity; such is not an art-recognized property of VEGF, and is neither described or enabled by the

specification as originally filed. While Carlevaro et al., cited by applicants , teach that VEGF is *associated* with neovascularization in cartilage, such is not equivalent to bone growth. Further, the finding that chondrocytes express VEGF is also not indicative of bone growth induction *by* VEGF. Bone growth is a complex process. While neovascularization is required for bone growth, and VEGF may be required for such neovascularization, presence of VEGF alone has not been shown to be a causative factor in induction of bone growth. Accordingly, the specification is not enabling of this property as applied to VEGF.

2) The specification does not provide adequate written description or enablement of the scope of claimed "second non-VEGF peptide portion" with angiogenesis or bone growth promoting activity.

For reasons similar to those above with respect to the "VEGF" portion of the protein, the written description and enablement are not commensurate in scope with any and all possible non-VEGF peptides. Once again, the specification has defined such in a manner that is so broad that any possible functional equivalent is encompassed. While there are numerous possible cytokines disclosed that could be the 'second' portion, the definitions in the specification encompass all possible derivatives of such, see for example paragraphs 0050-0051. As all functional equivalents of all possible proteins with the stated activity are encompassed, clearly the written description in the specification as originally filed does not support such, for reasons analogous to those above, and clearly enablement is not commensurate with such scope. With further respect to enablement, the Examiner notes the statement that the purpose of the invention is that "there remains a need for therapeutic fusion proteins which exhibit improved therapeutic potential over those presently known in the art". While the Examiner takes no issue with that statement, that is not a license for applicants to disclose and claim all possible such fusion proteins without any disclosure of the particular properties of the fusion proteins, and hence how such would be used. The claims, which encompass innumerable possible species, are merely an invitation to stick two proteins together and then discover what particular properties the combination has, and hence develop uses for such. Such

an invitation to experiment is not enabling.

3) There is no written description or enablement of fusion proteins with a half life at least twice as long as either the first or second peptide portion or both as claimed in claim 6, or of at least 10 minutes, as in claim 7. This is merely a desired property. The specification as filed does not disclose the half-lives of the various proteins, nor does it provide any data or working example of the half-life of any of the claimed fusion proteins. Half-life is a property of a protein, as well as of the biological system with which that protein is interacting. It is not recognized in the art that half-life is a predictable property. Hence, given the breadth of the claims, the lack of predictability in the art, the lack of guidance and absence of working examples, the specification is not enabling of proteins with the recited half-lives.

4) There is inadequate written description and enablement to support the scope of fusion proteins that result in vessels with less permeability than would result from "VEGF" administration (claim 10), or that result in vessels with greater maturity (claim 11), or that are associated with more smooth muscle cells, a greater concentration of smooth muscle cells, more endothelial cells, a greater concentration thereof, or a combination of such than would be obtained using only the 'VEGF' portion of the protein (claim 12), all of the aforementioned points applying both generically and with respect to the elected species of second peptide, HBNF. Once again, the claim is merely stating a desired property of the claimed protein, and the specification does not provide guidance as to what types of proteins provide such properties, or how one would modify a protein to do so. Merely disclosing a few proteins that might have one of the claimed properties is insufficient to describe or enable the scope of the claims which encompass any and all proteins having said properties, for reasons cited above. With particular respect to the elected species, HBNF, none of those properties have been recognized as being associated with HBNF in the art, and the specification provides no guidance or working examples of HBNF with such properties. As stated above, the art of protein engineering is unpredictable, and it would not be expected that HBNF could be engineered to have

such properties without undue experimentation. Accordingly, such is not enabled for the elected species.

5) With respect to the elected species, HBNF, there is no enablement that the fusion protein will diffuse farther than a protein consisting of a heparin-binding form of VEGF (claim 14). Once again, applicants are choosing to claim the proteins by physical properties of such. While it would reasonably be expected that fusion proteins that do not bind components of the extracellular matrix would diffuse better than those that do, HBNF is known in the art to bind to the extracellular matrix; Imai et al., cited by applicants (Journal of Biological Chemistry) disclose that HBNF binds to syndecan, a component of extracellular matrix. The specification provides no guidance as to whether the syndecan binding of HBNF causes higher or lower diffusion than heparin-binding by VEGF. It is not predictable, and the Examiner could find no comparison in the art of the relative affinities for the two substrates. Accordingly, it is not predictable what the diffusion properties of HBNF fusion proteins would be relative to those of VEGF, the specification provides neither guidance nor working examples of such, and such is not enabled for the elected species.

6) There is inadequate written description and enablement to support a claim that requires that the protein diffuse through the extracellular matrix farther than a protein consisting essentially of the second peptide portion (claim 15). The second peptide portion is specified only by function, as discussed above. While the claims require that the VEGF portion of the protein *not* bind heparin, there is no description of what things may or may not be bound by the second portion of the molecule, nor how the presence of a non-heparin binding VEGF moiety would affect diffusion of the molecule. There is no written description or guidance as to how such is to be achieved, and no working examples. Accordingly, the examiner concludes that the specification does not describe or enable this property.

7) There is inadequate written description and enablement to support claims to proteins having the

properties recited in claim 17, both generically and with respect to the elected species. Claim 17 lists a number of additional properties of the second peptide. In addition to the lack of written description and enablement of the second peptide itself for reasons above, there is no written description or guidance as to how such is to be achieved, and no working examples. Accordingly, the examiner concludes that the specification does not describe or enable these properties. Although they may be possessed by one or more species, the specification has not provided guidance as to which species, or how to make such. With respect to the particularly elected species, HBNF, once again, none of these properties have been reported for HBNF, the specification has neither described species of HBNF with those properties, nor has it enabled how to make or use such.

8) The specificaton has not taught how to use proteins comprising VEGF and HBNF. Papadimetriou et al., cited by applicants, disclose that soluble HBNF had *no* effect on the proliferation of bovine brain capillary cells, HUVEC, or rat adrenal medulla microvascular endothelial cells. Therefore, it is not predictable that a soluble fusion protein comprising HBNF would be able to do otherwise. Imai et al., also cited by applicants, disclose that HBNF "is expressed by osteoblasts/osteoplast precursors", is extracellular matrix-associated, and binds syndecan. Imai et al. also reported that soluble HBNF inhibited osteoblast recruitment in a dose dependent manner (see Fig. 3). Thus, one of ordinary skill in the art would not expect a soluble protein comprising HBNF to *promote* bone growth. With respect to angiogenic activity, Choudhuri et al., cited by applicants, report angiogenic activity of HBNF on breast carcinoma cells. However, this is not predictive of angiogenic activity on other cells, and would not be predictive of how to use HBNF to stimulate angiogenesis. This conclusion is supported by Relf et al., cited by applicants, who state that "Angiogenesis in tumors, however, is quite different from that seen in normal tissues, with leaky vessels, aberrant blood flow, and areas of necrosis, as well as increased vascularity." Hence, although HBNF may have angiogenesis-related activity in mammary tumors, the art does not recognize it as an angiogenic factor, and neither the art nor the specification as filed have taught how to use it for such; what types of cells, and under what conditions. Further, HBNF in a breast carcinoma and the test systems used

making a cytotoxic fusion protein to be used to treat either KS or glioma/glioblastomas. The artisan would have been motivated to do so by the disclosures of Gill et al. and Rockwell et al. that the VEGF receptors are 'markers' for those tumors, and would have been particularly motivated to use the 121 amino acid form of VEGF, as it is the shorter of the soluble forms (see col. 1 of Rockwell et al.), and the art generally recognizes the utility of using smaller molecules where possible, for example see Yoon et al. Accordingly, the invention, taken as a whole, is *prima facie* obvious over the cited prior art.

Advisory Information:

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Lorraine M. Spector, whose telephone number is (703) 308-1793. Dr. Spector can normally be reached Monday through Friday, 9:00 A.M. to 5:30 P.M.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Dr. Gary L. Kunz, at (703)308-4623.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist at telephone number (703) 308-0196.

Certain papers related to this application may be submitted to Group 1800 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1 (CM1). The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). NOTE: If Applicant *does* submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Official papers filed by fax should be directed to (703) 872-9306 (before final rejection) or (703)872-9307 (after final). Faxed draft or informal communications with the examiner should be directed to (703) 746-5228.

Lorraine Spector, Ph.D.
Primary Examiner

09/832355.1
10/20/02

by Choudhuri et al. was in membrane bound form, and not soluble, as it would be in the claimed fusion protein. As taught by Papadimetriou and discussed above, the activity of membrane-bound HBNF is not predictive of the activity of soluble HBNF. Finally, there are no reports in the art of any role for HBNF in wound healing, as in claim 30.

Thus, the only predictable activities of the claimed soluble protein comprising VEGF and HBNF are angiogenic activity due to the VEGF, neurite outgrowth activity due to the HBNF, and the ability to inhibit osteoblast recruitment, due to the HBNF. The specification as originally filed has not taught how to use a protein with those properties; it is not clear for what conditions or methods of treatment such a protein would be desirable. Accordingly, the specification as originally filed fails to teach how to use the elected species.

9) There is inadequate written description and enablement of proteins 30% of more homologous to the elected species HBNF (claim 29). In addition to the lack of enablement in the paragraph above, the specification does not adequately teach how to modify HBNF in a manner commensurate in scope with claims encompassing homologues only 30% identical to such. See paragraph 1) above with respect to VEGF; this situation is similar, as there is no guidance, description, nor working example of a single species of protein only 30% identical to HBNF that would function as claimed, and it would, considering the unpredictability in the art, require undue experimentation to make such.

10) Enablement is not commensurate in scope with claims to truncated forms of N-terminally truncated HBNF having less than 50% of the protein. Inui et al., J. Peptide Research, cited by applicants, teach that the C-terminal 50% of the HBNF protein is responsible for its biological activity. However, having identified that, it is increasingly unpredictable that more of the molecule can be removed without loss of activity. Once again, the specification has provided no guidance or working examples as to what additional 10% might be removed without affecting activity. It would take undue experimentation to make a commensurate number of such species, especially considering the uncertainty of HBNF activity itself, see paragraph 8) above.

11) There is inadequate written description and enablement for vectors expressing a second protein as claimed in claim 38, including the method of claim 42, which requires that the second protein be expressed in a manner to 'imitate a biological cascade associated with angiogenesis, bone growth, or wound healing'. The 'biological cascades' associated with angiogenesis, bone growth and wound healing are not well understood, especially as they pertain to VEGF and HBNF. The specification as originally filed does not provide a written description of those cascades, nor guidance as to how to imitate such. The claims appear to be an invitation to experiment to do so, and are not supported or enabled by the specification as originally filed. Such would require specific expression of specific activities at specific times in the claimed processes; no written description or enablement of such is found.

Rejections Over Prior Art:

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (e) the invention was described in-
> (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or
> (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

Claims 1-4, 9, 10, 14, 16-19, 32-34, 39-40, and 43-45 are rejected under 35 U.S.C. 102(a) as being anticipated by Davis et al., WO 00/37642, cited by applicants.